



Job Title	Senior Director, AOC Analytical Development & Quality Control
Position Type	Full-Time
FLSA	Exempt
Department	Tech Ops/CMC
Reports To	Vice President, Tech Ops
Salary Range	\$264,00 - \$291,000

**Job Summary:**

The Senior Director/Director of AOC Analytical Development & Quality Control will lead analytical strategy and quality control activities for oligonucleotide, monoclonal antibody (mAb), AOC drug substance and product across all development phases. This role is responsible for establishing robust analytical methods, ensuring compliance with regulatory requirements, and supporting CMC activities from early development through commercialization. The ideal candidate will have deep expertise in analytical method development and validation, stability programs, and experience managing teams and external partners.

**Job Responsibilities:**

- Lead analytical development and QC strategy for oligonucleotide, mAb, AOC DS and DP programs across early and late phases. Most work will be conducted at third party CROs and CMOs
- Develop, qualify, and validate analytical methods for oligonucleotide, mAb, AOC drug substances and drug products.
- Oversee QC activities, including release and stability testing, in compliance with cGMP requirements.
- Provide subject matter expertise on characterization, impurity profiling, and specification setting for oligonucleotides and mAbs/AOCs.
- Collaborate with CMOs and internal teams to ensure timely execution of analytical and QC deliverables.
- Support regulatory filings by authoring and reviewing analytical sections of INDs, amendments, and BLAs.
- Drive late-stage analytical activities, including method validation, comparability studies, and lifecycle management.
- Ensure robust stability programs and shelf-life extensions for oligonucleotide and mAb/AOC products.
- Partner with QA, Process Development, and Regulatory Affairs to maintain compliance and readiness for inspections.
- Identify and mitigate risks related to analytical and QC activities impacting clinical and commercial supply.
- Adhere to applicable regulations, including FDA, EMA, ICH, and Atrium policies.

**Education and Experience Requirements:**



- Bachelor's degree in chemistry, biochemistry, pharmaceutical sciences, or related field required; advanced degree (MS/PhD) preferred.
- Minimum 10 years of pharmaceutical industry experience in analytical development and QC for oligonucleotides and/or mAbs/AOC.
- Proven experience managing analytical development teams and external partners.
- Expertise in analytical techniques for oligonucleotides (e.g., LC, LC-MS, CE, UV) and mAbs/AOC (e.g., HPLC, CE-SDS, peptide mapping, glycan analysis, charge variants).
- Hands-on experience with method development, validation, and regulatory requirements for late-stage clinical and commercial manufacturing.
- Strong understanding of GMP, ICH, FDA, and EMA guidelines.
- Prior experience supporting IND and BLA/NDA filings and response to questions.
- Excellent leadership, communication, and problem-solving skills.
- Ability to manage multiple priorities in a fast-paced environment

#### **Knowledge, Skills and Abilities:**

- Excellent interpersonal skills, ability to work in a matrix environment and develop relationships with key stakeholders.
- Excellent communication and presentation skills to efficiently relay information to staff, project teams, executive leadership and other key stakeholders
- Proven ability to work independently and be self-motivated

#### **Work Environment & Physical Requirements**

- This position operates in a professional office and/or laboratory environment.
- Standard office equipment such as computers, phones, photocopiers, filing cabinets, and fax machines are used regularly.
- The role may occasionally require work in controlled laboratory or manufacturing settings, following applicable safety and PPE requirements.
- Noise levels are generally low to moderate, consistent with office or lab environments.
- Some roles may involve occasional travel between company sites or to external meetings, conferences, or events.
- Prolonged periods of sitting at a desk and working on a computer.
- Frequent communication with others, including speaking, hearing, and seeing to exchange accurate information.
- Occasional standing, walking, bending, or reaching may be required.



- Must be able to lift up to 20 pounds occasionally (e.g., office materials or lab supplies).
- Specific roles may require the use of specialized lab equipment, manual dexterity, or fine motor skills.
- Many of the essential functions of this role are captured by the Job Responsibilities, Knowledge, Skills and Abilities, Work Environment and Physical Requirements. The company is committed to providing reasonable accommodations to qualified individuals with disabilities to enable them to perform the essential functions of their jobs, in accordance with applicable federal, state, and local laws.
- Job descriptions are intended to describe the general nature and level of work performed; they are not an exhaustive list of all responsibilities, duties, and skills required. Other duties may be required